

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

BOZDAYI

Atty. Ref.: 2551-158

Serial No. 10/509,094

Group: 1648

Filed: September 28, 2004

Examiner: Kinsey

For: HBV DRUG RESISTANCE DRUG RESISTANCE
DETECTION METHODS

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

September 17, 2007

Sir:

INFORMATION DISCLOSURE STATEMENT

- ☐ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**
[within 3 months of filing or prior to 1st Office Action on the merits]
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
N/C
- ☒ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**
[after Final Office Action or Allowance (requires Rule 97(e)
Statement and Rule 17(p) fee), but before final fee payment]
\$180.00

The following are submitted in the above-identified application in compliance with
37 C.F.R. §§ 1.97 and 1.98:

- ☒ 4. A list of documents on Form PTO-1449 together with copies of each identified document and a translation or a concise explanation of each non-English language document (such as a Search Report) is enclosed herewith. The relevance of H. Uetake Ed., Virology, 4th Ed., ver.1, Rikougaku-sha (publ.), July 10, 2002, p 452 (in Japanese) is noted in Aoyama & Partners letter dated February 15, 2007, which relates to the Office Action wherein the noted Japanese reference was cited.

This paper is submitted in accordance with:

- ☐ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☒ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
- ☐ a) The required Statement made in item 8 below; or
- ☒ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
- ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
- ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
- ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
- ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this

Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

Respectfully submitted,
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**INFORMATION DISCLOSURE
CITATION**

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10/509,094

APPLICANT

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2003-0124096 A1	7-2003	Locarnini			
	6555311	4-2003	Locarnini			
	2007-0042356	2-2007	Schildgen			
	2006-0165725	7-2006	Bozdayi			
	2006-0234212	10-2006	Bozdayi			

FOREIGN PATENT DOCUMENTS

		DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	1	WO 94/26904	11-1994	WIPO				
	29	97/40193	10/1997	WIPO				
	32	03/087351	10-2003	WIPO				
	33	2004/031224	4-2004	WIPO				
	34	03/066841	8-2003	WIPO				

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27	Aye <i>et al</i> , "Hepatitis B Virus Polymerase Mutations During Famciclovir Therapy in Patients Following Liver Transplantation", Hepatology Vol. 24, No. 4, Pt.2, Abstract 633, September 1996
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38	Bartholomeusz <i>et al</i> , "Mutations in the hepatitis B virus polymerase gene that are associated with resistance to famciclovir and lamivudine", 1997, International Antiviral News, Vol. 5, No. 8, 123-124
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14	BOWYER S <i>et al</i> , J General Virology (1997), vol. 78, pp 1719-29, "A unique segment of the hepatitis B virus group A genotype identified in isolates from South Africa" Figure 5
17	Carman <i>et al</i> , "Vaccine-induced escape mutant ...", The Lancet, Vol. 336, 1990 (8711) pages 325-329.
20	Carman, "The clinical significance of surface antigen variants ...", Journal of Viral Hepatitis, 1997. 4 (Suppl. 1) 11-20.
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*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	SERIAL NO.
	2551-158	10/509,094
(Use several sheets if necessary)	APPLICANT	
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24	Fischer et al, "Generation of Duck Hepatitis B Virus Polymerase Mutants through Site-Directed Mutagenesis Which Demonstrate Resistance to Lamivudine [(-)-β-L-2',3'-Dideoxy-3'-Thiacytidine] In Vitro", Antimicrobial Agents & Chemotherapy 40: 1957-1960, August 1996
18	Fujii et al, "Gly ¹⁴⁵ to Arg Substitution in HBs Antigen of ...", Biochemical and Biophysical Research Communications, Vol. 184, No. 3, May 15, 1992, pages 1152-1157.
44	Ho et al, "A Family Cluster of an Immune Escape Variant of Hepatitis B Virus Infecting a Mother and Her Two Fully Immunized Children", Clinical and Diagnostic Laboratory Immunology, 1995, Vol. 2, No. 6, pp 760-762
9	HORIKITA M <i>et al</i> , J Medical Virology (1994), vol. 44(1), pp 96-103, "Differences in the entire nucleotide sequence between hepatitis B virus genomes from carriers positive for antibody to hepatitis B e antigen with and without active disease" Table IV.
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10	NI F <i>et al</i> , Research in Virology (1995), vol. 146(6), pp 397-407, "A new immune escape mutant of hepatitis B virus with an Asp to Ala substitution in aa144 of the envelope major protein" Figure 3.
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7	NORDER H <i>et al</i> , J General Virology (1992), vol. 73(5), pp 1201-8, "Comparison of the amino acid sequences of nine different serotypes of hepatitis B surface antigen and genomic classification of the corresponding hepatitis B strains" Figure 3.
8	NORDER H <i>et al</i> , J General Virology (1993), vol. 74, pp 1341-8, "Genetic relatedness of hepatitis B viral strains of diverse geographical origin and natural variations in the primary structure of the surface antigen" Figure 2.
5	OKAMOTO F <i>et al</i> , J. General Virology (1988), vol 69, pp. 2575-83, "Typing hepatitis B virus by homology in nucleotide sequence: comparison of surface antigen subtypes" Figure 1.
3	ONO Y <i>et al</i> , Nucleic Acids Research(1983), vol. 11(6), pp 1747-57, "The complete nucleotide of the cloned hepatitis B virus DNA; subtype <i>adr</i> and <i>adw</i> " Figure 2 and 3.
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47	Perrillo et al, "Adefovir Dipivoxil Added to Ongoing Lamivudine in Chronic Hepatitis B with YMDD Mutant Hepatitis B Virus", Gastroenterology 2004; 126:81-90
48	Poch et al, "Identification of four conserved motifs among the RNA-dependent polymerase encoding elements" EMBO Journal 8: 3867-3874, 1989
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6	RIVKINA M <i>et al</i> , Gene (1988), vol. 64, pp. 285-96, "Nucleotide sequence of integrated hepatitis B virus DNA and human flanking regions in the genome of the PLC/PRF/5 cell line" Figure 5.
50	Stuyver <i>et al</i> , "Nomenclature for Antiviral-Resistant Human Hepatitis B Virus Mutations in the Polymerase Region", Hepatology 2001; 33:751-757
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59	Kan Tan Sui, "Escape Mutants of HBs" (1993), 27(4), pp 555-562
60	H. Uetake Ed., Virology, 4 th Ed., ver.1, Rikougaku-sha (publ.), July 10, 2002, p 452 (in Japanese) (Relevance noted in Doc. No. 61)
61	Aoyama & Partners letter dated February 15, 2007, relating to Japanese Patent Application No. 521944/1998 (4 pages)
62	Aoyama & Partners letter dated January 25, 2007, relating to Japanese Patent Application No. 521944/1998 (2 pages)
63	Aoyama & Partners letter dated July 23, 2007, relating to Japanese Patent Application No. 521944/1998 (1 page) with English translation of amended claims (2 pages) and copy of Amendment filed July 19, 2007, in response to Official Action (11 pages)

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